



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0233]

Center for Drug Evaluation and Research; Use of Innovative Packaging, Storage, and/or Disposal Systems to Address the Misuse and Abuse of Opioid Analgesics; Request for Comments; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to receive suggestions, recommendations, and comments on innovative packaging, storage, and disposal systems, technologies or designs (“designs”) that could be used to prevent or deter misuse and abuse of opioid analgesics by patients and others. FDA is interested in receiving comments on new designs as well as enhancements to existing designs, and is particularly interested in comments from academic institutions, regulated industry, technology companies (e.g., those producing technologies for medication adherence, disposal, or tracking), healthcare professionals, patient representatives, clinical trial service providers, and other interested organizations. Comments submitted in response to this notice will help the Agency determine whether innovative designs for opioid analgesic packaging, storage, and/or disposal systems could help prevent or deter misuse and abuse without diminishing access for patients with legitimate prescriptions.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-301), Food and Drug Administration, 5630 Fishers Lane, m. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Colleen Brennan, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4410, Silver Spring, MD 20993-0002, 301-796-2316, email: Colleen.Brennan@fda.hhs.gov, with the subject line identified as “Packaging Abuse Deterrence Strategies.”

SUPPLEMENTARY INFORMATION:

I. Background

Prescription opioid analgesics are important medications that are widely prescribed for the treatment of both non-cancer and cancer-related pain. When used properly for their approved indications, opioid drugs provide significant benefits for patients. However, they also carry a risk of misuse, abuse, addiction, overdose, and death. According to an analysis from the Centers for Disease Control and Prevention, in 2010, prescription opioid drugs were involved in 16,651 overdose deaths, which represented a 313 percent increase over the past decade (Ref. 1). The Substance Abuse and Mental Health Services Administration (SAMHSA) reports that for each overdose death, there were an additional 11 treatment admissions (Ref. 2), 33 emergency department visits (Ref. 3), and 880 non-medical users of these drugs (Ref. 4).

Although inappropriate or illicit use, such as sharing the drug with family and friends or using drugs stolen from home medicine cabinets account for some of the problems with prescription opioids, legitimate use of opioids for pain may also lead to adverse events, addiction, and death. FDA plays a central role in the development, review, and approval of opioid drug

products and must strike a balance between their benefit in the legitimate treatment of patients with pain and the risks to those patients and others associated with misuse, abuse, and addiction.

Combating opioid misuse, abuse, and addiction has long been both a public health priority and a priority for the Agency. FDA has taken many steps to address these problems; however, we recognize that more can be done and have established a task force that has embarked on a multi-pronged approach, building upon existing initiatives and developing new initiatives (<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337852.htm>). Exploring innovative designs for drug packaging, storage, and/or disposal is one of the many initiatives targeted by the task force.

Designs for drug packaging, storage, and disposal have evolved considerably in the past decade to include many technology-based features such as electronic systems for monitoring, assessing, and improving adherence to medication regimens. For example, these systems may include functionality to remind patients to take a dose, track when a dose is taken and how much is taken, and limit further access until it is time for the next dose. Additionally, many of these drug-device combinations electronically encrypt and capture the accumulated adherence data, which can be downloaded directly from the device or wirelessly transmitted to the prescriber. These technologies have not only been used in clinical management and monitoring of protocol compliance in clinical trials, but have also been applied to combat the problem of prescription opioid misuse and abuse.

Other potentially relevant technologies include “track and trace” capabilities, radio-frequency identification-based systems, microchips embedded within tablets, and in-home medication deactivation and/or disposal systems.

FDA is interested in further exploring the role of existing and innovative designs for drug product packaging, storage, and/or disposal in mitigating opioid misuse, abuse, and addiction.

For example, many of the features of medication adherence monitoring technologies could be used or adapted to help prevent serious complications (e.g., overdose, addiction) by supporting proper dosage and administration, and could also help prescribers monitor for signs of abuse or medication sharing by facilitating effective patient management and followup. Additionally, medication packaging and/or storage designs that limit access could help prevent use of the medication by someone for whom it was not prescribed, thereby, preventing accidental exposure (e.g., by a child or other household contact) or theft. Finally, medication packaging, storage, and/or disposal designs could be applied or adapted to help ensure safe disposal, including chemical deactivation, of any unused or residual medication.

II. Establishment of a Docket

FDA is announcing the establishment of a public docket to provide an opportunity for interested persons to share information, research, and ideas on how drug product packaging, storage, and/or disposal systems could be designed or adapted to address problems associated with prescription opioid abuse and misuse. These comments will help the Agency explore whether existing or innovative designs can be applied or adapted to prevent or deter misuse and abuse, while ensuring that patients in pain have appropriate access to opioid analgesics.

III. Suggestions for Those Submitting Comments in Response to This Notice

Proposed packaging, storage, and/or disposal designs should be feasible to implement, and should not impair access for patients who have legitimate prescriptions. Comments about specific system or technology designs should include a description of the following: (1) Design features and functionality; (2) results of any formative or summative human factors assessments conducted; (3) applications to date, including information on the effectiveness and acceptability of those applications (with literature references or other documentation); (4) recommendations for how the system/technology design could be applied or adapted (either alone and/or in

combination with other systems/technologies) to help prevent or deter misuse and abuse, and any limitations of that application; (5) specific problems that could be addressed (e.g., serious complications such as addiction or overdose due to improper dosage and/or administration, improper disposal, accidental use by someone for whom the medication was not prescribed); and (6) to the extent possible, considerations for implementation into routine dispensing and clinical use (e.g., how the solution would impact the workflow in a retail pharmacy).

To help FDA prioritize among proposed approaches, the Agency is also interested in receiving feedback about methods that could be used to assess a system or technology's potential abuse-deterrent characteristics and real-world impact (e.g., actual ability to prevent or deter misuse and abuse, effect on access for appropriate patients, patient confidentiality, burden on the healthcare system, feasibility of implementation, whether the design could create unintended medication errors). Finally, FDA is interested in receiving feedback on methods for encouraging further research and development in this area, and, if promising technologies are identified, incentivizing the pharmaceutical industry (e.g. via patent extensions) to adopt such technologies.

IV. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>. The Agency will carefully consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the comment.

V. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Centers for Disease Control and Prevention. “Opioids drive continued increase in drug overdose deaths” [Press Release] (2013).

http://www.cdc.gov/media/releases/2013/p0220_drug_overdose_deaths.html.

2. SAMHSA, Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set (TEDS): 2001-2011. National Admissions to Substance Abuse Treatment Services. BHSIS Series S-65, HHS Publication No. (SMA) 13-4772. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

3. SAMHSA, Center for Behavioral Health Statistics and Quality, “Drug Abuse Warning Network,” 2011. http://samhsa.gov/data/dawn/nations/Nation_2011_AllMA.xls.

4. Substance Abuse and Mental Health Services Administration, Results from the 2012 National Survey on Drug Use and Health, detailed table 1.1A, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

Dated: April 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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